APR - 1 2004

K030989

510 (k) Summary

a. Device Classification Name:
Plate, Bone
b. Regulation Class / Number:
Class II, Section 872.4760
c. Device Name:
OsteoSorb® Tack Fixation System
d. Product Code:
JEY
e. Classification / Review Advisory Committee:
Dental

The OsteoSorb® Tack Fixation System Consists of resorbable tacks and accessory instruments, which are additional components of the Osteomedics® Resorbable Small Fixation System OsteoSorb® (K022035). Resorbable tacks are available in 1.5 mm diameter and in lengths ranging from 4-8 mm. The emergency tack system consists of 1.7 mm in diameter. The OsteoSorb® Tack Fixation System are similar in design to the standard screw in the Osteomedics® Resorbable Small Fixation System OsteoSorb® (K022035) however the tacks are designed with barbs that are pushed into a drilled hole that is slightly smaller than the diameter around the barbs. An instrument set consists of crossbow type inserter and bone drill. Basic elements are the drilling of hole for the tack, which is completely the same step than with the conventional screws. Then the tack is pushed into hole with inserter. There is no need for tapping the hole and screwing like with the conventional screws. The material for the OsteoSorb® Smooth Pin Fixation System is Poly (L/DL-Lactide).

The OsteoSorb® Tack Fixation System is intended for fractures of craniofacial skeleton including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital area, comminuted fractures of the frontal sinus wall, and midfacial fractures; and reconstructive procedures of the midface or craniofacial skeleton. The OsteoSorb® Tack Fixation System stabilizes bone during healing in conjunction with appropriate postoperative immobilization.
The OsteoSorb® Tack Fixation System stabilizes bone during healing in conjunction with appropriate postoperative immobilization. The Osteomedics® Resorbable Tack Fixation System is not intended for use in and is contraindicated for: 1) Significant comminuted fractures or area with active infection; 2) Patient conditions including: blood supply limitation, insufficient quantity or quality of bone, or latent infections and where patient co-operation can not be guaranteed (e.g. alcoholism). 3) Mandibular tumor resection 4) Intermaxillary fixation without an appropriate external fixation by other means 5) This device is not designed for use in the mandible or for use in full load bearing procedures.6) when time to healing is anticipated to be greater than six weeks, and when patient has a history of adverse reaction to resorbable materials (e.g. resorbable sutures). The OsteoSorb® Tack Fixation System are similar in design to the standard screw however tacks are designed with barbs that are pushed into a drilled hole that is slightly smaller than the diameter around the barbs. There is no need for tapping the hole and screwing like with the conventional screws. Federal (USA) laws restrict this device to sale or on the order of a physician.

510 (k) Summary

a. Device Classification Name:
Pin, Fixation, Smooth

b. Regulation Class / Number:
Class II, Section 888.3040

c. Device Name:
OsteoSorb® Smooth Pin Fixation System

d. Product Code:
HTY
e. Classification / Review Advisory Committee:
Orthopedic

The OsteoSorb® Smooth Pin Fixation System consists of a series of bioabsorbable pins in various length and diameter. Pin diameters are; 1.3,1.5,2.0 and 3.2 mm with lengths of 10, 20, 30, 40, 50, 60 and 70 mm The pin can be shortened intra-operatively to as little as 10 mm. The material for the OsteoSorb® Smooth Pin Fixation System is Poly (L/DL-Lactide).

The OsteoSorb® Smooth Pin Fixation System intended for use in the presence of appropriate immobilization for the internal fixation of fractured non-load bearing bones, osteotomies and arthrodeses, for example in fixation of apical fragments, osteochondral fragments and cancellous / non-load bearing fragments. Correction of hallux valgus and repair of metacarpal and phalageal fusion and fracture.

The OsteoSorb® Pin Fixation System stabilizes bone during healing in conjunction with appropriate postoperative immobilization.Use is contraindicated in case where conservative (closed) treatment is appropriate, where pressure osteosynthesis is desired, where fragments are subjected to tension stress, when time to healing is anticipated to be greater than six weeks, when patient has a history of adverse reaction to resorbable materials (e.g. resorbable sutures), when use of the device without appropriate postoperative immobilization, when fractures and osteotomies is in weight bearing bone, where internal fixation is otherwise contraindicated, e.g., insufficient quantity or quality of bone and where patient co-operation cannot be guaranteed (e.g. alcoholism) where significant comminuted fractures or area with active infection. Federal (USA) laws restrict this device to sale or on the order of a physician.

P3 K050959

510 (k) Summary

a. Device Classification Name: Plate, Bone b. Regulation Class / Number: Class II, Section 872.4760 c. Device Name: HeatingPen and HeatingBath d. Product Code: JEY e. Classification / Review Advisory Committee: Dental	a. Device Classification Name: Pin, Fixation, Smooth b. Regulation Class / Number: Class II, Section 888.3040 c. Device Name: HeatingPen and HeatingBath d. Product Code: HTY e. Classification / Review Advisory Committee: Orthopedic

The Noviace HeatingPen

The Noviace HeatingPen is used for plate bending and cutting plate, screw tip and pin. The HeatingPen device enables to mold in-situ OsteoSorb Plates to varying skeleton morphologies. The HeatingPen is a single-use, cordless and battery operated. Three (3) tips are provided – a cautery tip which is used to cut plates, screw tips and pins, a long malleable plate tip, and a short fixed plate tip, both of which will bend plates in–situ.

Do not attempt to resterilize HeatingPen; this is a single-use device.
Do not use in presence of flammable materials.
Remove tip before discarding.
Remove batteries and dispose in recycling receptacles before discarding.
Federal (USA) laws restrict this device to sale or on the order of a physician

P4 K060989

The NOVIACE HeatingBath

The Noviace HeatingBath is used to shape intra-operatively the OsteoSorb® Plate and Mesh. The Noviace™ HeatingBath is consisting of heating unit and auxiliary pan, which are fabricated from PolarWare 304 Stainless Steel. The heating unit sold non-sterilized but the auxiliary pan is sold sterilized.

The Noviace HeatingBath will get hot.
The heating unit of the Noviace HeatingBath is non- sterilized.
The auxiliary pan of the Noviace HeatingBath is sterilized.
The auxiliary pan of the Noviace HeatingBath is a disposable unit and must not to be reused.
The sterilized auxiliary pan must be inserted into heating unit prior to use.
Do not operate the heating unit without sterilized auxiliary pan.
Do not operate the unit with out sterile water or sterile saline in the auxiliary pan.
Do not place hand into auxiliary pan, use forceps to place or remove OsteoSorb® Plates and Meshes.
The unit will reach at desired temperature of 140° F (60° C) within 30 minutes.
Do not use in presence of flammable materials.
Do not attempt to autoclave or sterilized heating unit or auxiliary pan.
Do not immerse Noviace HeatingBath.
Do not use flammable liquids in this unit, use only sterile water/saline via sterile auxiliary pan.
Use only water based cleaning solutions.
High Voltage inside of this unit, dangerous to unqualified persons.
Disconnect supply cord before opening.
Federal (USA) laws restrict this device to sale or on the order of a physician

Official Contact Person:
Albert Enayati
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Paramus, NJ 07652
Tel: (201) 444-7306
Fax: (201) 444-7395
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2004

Mr. Albert Enayati
President
Noviace Corporation
809 Carter Lane
Paramus, New Jersey 07652

Re: K030989
Trade/Device Name: OsteoSorb Tack and Pin Fixation System
Regulation Number: 872.4760, 888.3040
Regulation Name: Bone Plate, Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: II
Product Code: JEY, HTY
Dated: December 28, 2003
Received: January 12, 2004

Dear Mr. Enayati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K030989

Device Name: OsteoSorb Tack and Pin Fixation System

Indications for Use:

OsteoSorb® Tack Fixation System

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030989

K030989

OsteoSorb® Smooth Pin Fixation System

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Do not attempt to autoclave or sterilized heating unit or auxiliary pan.
Do not immerse Noviace HeatingBath.
Do not use flammable liquids in this unit, use only sterile water/saline via sterile auxiliary pan.
Use only water based cleaning solutions.
High Voltage inside of this unit, dangerous to unqualified persons.
Disconnect supply cord before opening.
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